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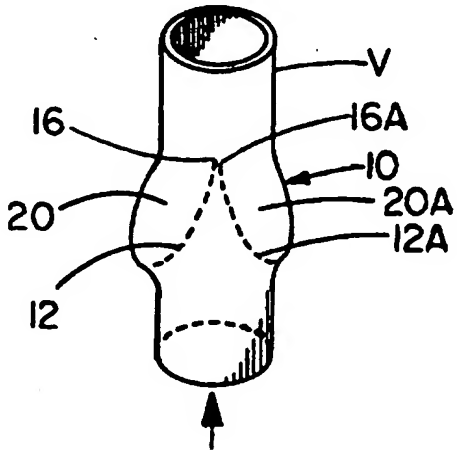
(54) Title: DEVICE FOR RESTORING COMPETENCE TO VENOUS VALVES

(57) Abstract

An implantable support device that is applied externally about a vein at an incompetent venous valve site which device serves to flatten or compress but not occlude the vein. Flattening is induced generally normal to the coapting edges of the valve cusps restoring the competence of the valve by causing an elongating tension to be applied to the free edges of the cusps to bring them into apposition. In the preferred embodiment, the support has opposed compression members fabricated from a biocompatible material and incorporates a reinforcing or spring-like member such as stainless steel wire to provide strength and rigidity.



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TITLE OF THE INVENTION

DEVICE FOR RESTORING COMPETENCE TO VENOUS VALVES

FIELD OF THE INVENTION

The present invention relates to a device for repairing incompetent venous valves and more specifically relates to an implantable support device which is positionable about a dilated vein to apply an external deformation force to a vein in the area of a venous valve, which force tends to flatten the valve and impart an oval shape to the vein. The flattening force is generally normal to the edges of the valve cusps, tensioning the cusp edges and bringing the valve edges into apposition to restore competence.

BACKGROUND OF THE INVENTION

Venous valves in humans and other animals are normally bicuspid valves in which each valve cusp forms a reservoir for blood under pressure which forces the free edges of the cusps together to prevent reflux. Incompetence is a condition in which the cusps do not properly coapt when a pressure differential or gradient is applied across a valve permitting reflux or retrograde flow of blood to occur. Medical literature indicates that many physicians believe that chronic venous insufficiency of the lower limbs is the result of deep venous thrombosis and associated inflammatory changes of venous valve cusps. Varicose veins often occur in the long saphenous veins in the lower legs when valve incompetence occurs. A varicose vein is considered to be a condition which occurs when a vein dilates and the tributaries become elongated and tortuous, resulting in cosmetic impairment, inflammatory phlebitis, pain and thrombosis.

When the valves of the varicose, long saphenous vein are examined, changes are evident including dilation, evagination between the cusps, and in later stages the membrane between the commissures thins and may have numerous fenestrae. These conditions are generally termed venous valve incompetence.

One of the most frequent symptoms of incompetence is poor coaptation of the valve cusps due to floppiness of the leading edges of the valve cusps. Reflux blood flow occurs both along the free edges of the cusps and in the corneal areas. Venous valve reconstruction

has progressed to the point that competence can be achieved by both internal and external repair techniques.

One of the surgical procedures to address this problem is application of sutures to the edges of the valve cusp leaflets in the corneal areas. The sutures are then pulled back and tied to the walls of the vein in order to reduce the length of the coapting edges of the leaflets. For example, the *Atlas of Venous Surgery* (1992), at page 125, discusses various valve reconstruction techniques for primary valve insufficiency. One technique is entitled "Internal Technique By Transvalvular Venotomy" involves first laying open the valve by performing a venotomy to expose the valve. The object of the repair is to shorten the leading edge of each cusp to restore a cup-like configuration to both cusps in a procedure termed internal valvuloplasty. The valve is repaired with monofilament suture at three locations, medial, lateral and posterior until the leading edges of the two valves lie gently across the face of the vein with the floppy, rugal folds eliminated.

Another internal method of valve repair is described in PCT Publication WO93-01764. This publication describes an intravenous device that may be used to partially or totally flatten a vein. The device consists of two bearing rods which are connected by at least one spreader element having a spring effect which are capable, when inserted into the lumen of the vein, to apply an outward force on the two opposite sides of the vein so that it pushes the commissures of the vein apart, flattening the vein and thus improving coaptation. While effective, this device remains in the lumen of the blood vessel and may obstruct blood flow potentially contributing to thrombosis.

Restoration of venous valve competence can also be surgically achieved without performing venotomy by placing an external row of sutures along the diverging margins of the valve cusp insertion in the vein wall. Sutures for external repair are begun in each commissure on both sides of the vein. The advantage of external repair is that it can be done without venotomy and is less demanding technically than internal repair. External valvuloplasty is discussed in a number of recent articles including: "*The Role of External Banding Valvuloplasty in the Surgical Management of Chronic Deep Venous Disease*", H. Schanzer et al., Phlebology (1994) 9:8-12; "*External Valvuloplasty of the Saphenofemoral Junction*"; P. Zamboni et al., Vascular Surgery, Vol. 28 No. 5, June 1994. Zamboni et al., describe the use of porous PTFE material to surround an incompetent venous valve whereby the region of the venous valve is forced into a round or circular transverse cross section.

Other surgical approaches involve venous valve transplant in which replacement of a segment of the vein having the incompetent valve occurs with the segment of another vein having a competent valve being surgically interposed.

These surgical methods, while all successful to some degree, require a high degree of surgical skill and often result in a temporary repair. Internal repairs also may result in reducing or narrowing of the internal vein lumen, obstructing blood flow.

Another approach to restore competence of incompetent venous valves involves reducing the diameter of the appropriate vein at the valve site. In this approach, a cuff is applied around the vein which cuff consists of a band of biocompatible, implantable material that is not stretchable, at least at blood flow pressures. The band is of sufficient length to encompass the vein at the valve site with the ends of the band overlapping. The cuff is attached by a special applicator which reduces the circumference of the cuff until competence is restored. This system reduces the diameter of the lumen to restore competence. Reference is made to U.S. Patent No. 5,147,389 entitled "Correction of Incompetent Venous Valves" which describes such a system and which system is currently available and known as the "Venocuff"™ system. Use of a Dacron® (registered trademark of E.I. Du Pont de Nemours & Co., Inc.) graft used as a cuff about the vein is discussed in "*A Method For Repairing Incompetent Valves In Deep Veins*", Dag Hallberg, Acta Chirurgica Scandinavica, 138:143-145 (1972). The above device, however, does not improve coaptation of excessively elongated edges of venous valve cusps.

U.S. Patent 5,441,509 shows a surgical clip having a monolithic hinge with projecting legs for compressing a vessel or tissue but are not implantable and are generally intended for temporary occlusion of a vessel.

Various surgical clips are also known. For example, U.S. Patent 5,441,509 describes a surgical clip intended to occlude various anatomical structures. While such surgical clips relate to methods of occlusion, none describe external methods of improving the effectiveness of venous valves while avoiding occlusion of the vein.

In view of the foregoing, it is apparent there exists a need for a simple implantable device to effectively restore competence to incompetent venous valves at various locations in the venous system. Accordingly, it is a broad object of the present invention to provide an implantable support device that is applied externally to the vein to apply an external flattening of the vein at a venous valve site to restore competence of venous valves.

It is a further object of the present invention to provide a support device for applying restorative compression to the vein at a venous valve site, which device does not compress the sinus area of the valve.

It is yet another object of the invention to provide an implantable support device for restoring competence to an incompetent venous valve which device incorporates a biocompatible material and which device may be applied externally about the vein at a venous

valve site and secured in place by sutures or other mechanical means associated with the device.

These and other purposes of the present invention will become evident from review of the following specification.

SUMMARY OF THE INVENTION

The present invention involves an implantable support device that is applied externally about the vein at a venous valve site which device serves to flatten or compress but not occlude the vein. Flattening is induced generally normal to the coapting edges of the valve cusps restoring the competence of the valve by causing an elongating tension to be applied to the free edges of the cusps to bring them into apposition. In the preferred embodiment, the support has opposed compression members fabricated from a biocompatible material such as polytetra-fluoroethylene (hereinafter PTFE) or polyethylene terephthalate which incorporate a reinforcing or spring-like member such as stainless steel wire to provide strength and rigidity. In the preferred embodiment, the opposing members can be opened and closed along an intermediate hinge section and when closed over the vein, the members flatten the vein by applying a restorative force generally normal to the coapting edges of the valve. The support must have sufficient rigidity to maintain compression to impart an elliptical or oval shape to the vein sufficient to tension the cusp edges. The support may be provided in different sizes to assist the surgeon in properly applying the desired compressive force to different vein sizes and to treat different degrees of valve incompetence. The hinge section facilitates positioning the valve and the device may include a latching or locking member for securing the support about the vein. The support may also include relieved areas or recesses in the opposed compression members which relieved areas are positioned to be located over the sinus areas so that a compressive force is not applied to the sinus areas.

In other embodiments, the support may be fabricated from a biocompatible material such as that sold under the trademark GORE-TEX® Cardiovascular Patch manufactured by W. L. Gore & Associates, Inc. of Flagstaff, Arizona. The density and thickness of the material may be selectively varied in different areas of the support device to provide the desired compressive force and hinging. Still other useful materials from which the support may be made include fluorinated ethylene propylene, perfluoro alkoxy, polypropylene, polyurethane and resorbable polymers.

In yet another embodiment, the support may comprise a slightly ovoid helical winding of biocompatible material having reinforcing wire adhered to or incorporated into the winding. The support is extended and placed about the vein at the valve site and permitted to return to its ovoid shape to compress the vein to restore competence to the valve.

BRIEF DESCRIPTION OF THE DRAWINGS

The operation of the present invention should become apparent from the following description when considered in conjunction with the accompanying drawings, in which:

Figure 1 is a perspective view illustrating a vein and a typical venous valve site;

Figure 2 is a perspective view of a vein which has been partially cut away to expose the venous valve;

Figure 3 is a cross sectional view of a vein showing a competent venous valve;

Figure 4 is a view similar to Figure 3 showing a venous valve in which the valve edges and corneal areas are incompetent and permit reflux blood flow;

Figure 5 is a cross sectional view illustrating application of a normal force to the incompetent valve flattening the valve and bringing the leading edges of the valve cusps into apposition;

Figure 6 is a perspective view of a preferred embodiment of the venous valve support of the present invention;

Figure 7 is a plan view of the support of Figure 6 shown in laid open flat position;

Figure 8 is a perspective view of a vein with the support shown in Figures 6 and 7 applied thereto;

Figure 9 is a perspective view of another embodiment of the support of the present invention;

Figure 10 is a perspective view of yet another embodiment of the device of the present invention;

Figures 11 to 11B are representative cross sectional views of the support and a vein illustrating various configurations of the support to achieve vein flattening;

Figure 12 is a plan view showing yet another embodiment of the support of the present invention applied to a vein;

Figure 13 is a cross sectional view showing the support illustrated in Figure 12 applied to a vein;

Figure 14 is a sectional view taken along line 14-14 of Figure 12;

Figure 15 is a perspective view showing another embodiment of the support of the present invention in which multiple venous supports are formed as a series of interconnected helices;

Figure 16 is a view of a single helical support which comprises a single helix as compared to the series of multiple helices shown in Figure 15;

Figure 17 is an enlarged cross sectional view taken along line 17-17 of Figure 15; and

Figure 18 is a cross sectional view of a vein showing the support shown in Figure 16 thereon.

DETAILED DESCRIPTION OF THE INVENTION

Without intending to limit the scope of the present invention, the following examples illustrate how the present invention may be made and used:

Figures 1 to 3 illustrate a typical bicuspid venous valve 10 commonly found in humans and many animals. The valve 10 is located in a vein "V" at a valve site. The valve 10 has a pair of valve cusps 12 and 12A which are diaphanous, tough membranes, crescentic in shape. The blood flow direction is indicated by the arrow.The concave, coapting edges 16, 16A of the competent valve prevent reflux or retrograde flow in the opposite direction. The cusps are attached to opposite walls of the vein and meet at commissures 18, 18A, all of which together form sinuses 20, 20A.

In the normal competent valve, the free edges 16, 16A of the cusps will allow blood flow in the direction shown by the arrow and will restrict flow in the opposite direction. The sinuses 20, 20A and cusps 12, 12A form sacks or reservoirs for blood which force the edges 16, 16A together. The free edges of the cusps are in apposition in a competent valve generally along the axis A-A which will be termed the transverse axis of the vein and is coincident with the commissures.

When valve incompetence occurs, which may be due to inflammatory phlebitis, thrombosis or congenital factors which contribute to inherent or primary weaknesses of the vein wall, problems such as edema, pain and ulcerations can occur. Progressive development of varicose veins occur generally in the form of a dilatation near the valve, most frequently at the commissures, causing poor coaptation of the valve cusps due to enlargement of the commisural spaces and/or elongation of the leading edges of the cusps. Figure 4 illustrates this condition. The commissures 18 are distended and the free edges 16, 16A of the cusps are floppy and separated with numerous fenestrae permitting retrograde blood flow both at the free edges of the cusps and at the commissures. However, since veins are collapsible tubes,

when compressive force F is applied at opposite sides of the vein generally perpendicular to the axis A-A of the leading edges of the cusps, the vein will tend to flatten as shown in Figure 5. The flattening tends to elongate, tension and straighten the edges 16, 16A of the cusp substantially improving coaptation and reducing commissural spaces. It also serves to bring the valve cusps closer together. The force F should be applied normal to the cusp edges and exteriorly to the vein. This force F will assist in restoring competence to the valve by removing the slack or looseness of the free edges and bringing free edges of the cusps close together. It is important that the force F be applied so as not to restrict the vein and also it is desirable that the force F not be applied to restrict or compress the sinus areas of the vein which are aneurysm-like dilations in the valve. The basis for the present invention is the discovery that such application of external force when applied at the height of the coapting surfaces will flatten the vein and extend the cusps laterally bringing them into apposition restoring competence.

Turning to Figures 6 to 8, a support for applying a corrective flattening force to the vein in accordance with the present invention is shown. In this embodiment, the support is generally designated by the numeral 100 and, in Figure 8, is shown in connection with a vein "V" having distended sinus areas "S". The support 100 has a pair of opposite compression members 112, 112A which are identical and each is shown as being generally rectangular and each defining an aperture or relieved area 106. The members may have an elliptical or an arcuate configuration as seen in Figures 11 and 11B respectively or may be flat having curved ends as seen in Figure 11A. The members 112 are preferably fabricated from a biocompatible material such as porous, expanded PTFE, such as that sold under the trademark GORE-TEX Cardiovascular Patch as manufactured by W. L. Gore & Associates of Flagstaff, Arizona. This material has the structure of nodes interconnected by fibrils and is inert and has been demonstrated effective in vascular reconstruction.

The members 112, 112A are joined together by integrally formed intermediate hinge portion 114 which, when the support is positioned about a valve, generally extends axially with respect to the vein and is placed to be adjacent to one of the commissures 18, 18A. The width "W" of the hinge determines to some extent the compressive force applied by the support to the valve. A typical width for the hinge is from about 1 to 3 mm. The opposing members 112, 112A are positioned to apply a force generally normal to the free edges of the cusps so as to flatten the vein and tension the edges of the cusps as has been explained with reference to Figure 5. In order to provide the biasing force and the necessary strength and rigidity, reinforcing elements 110, 110A are attached to or embedded within the opposite compression members 112, 112A. The elements may be formed from a small diameter stainless steel medical grade wire, as for example MP35N. The wire may be formed into a

desired pattern to provide the biasing force and to reinforce compression members 112, 112A. In this embodiment, the spring-like elements 110,110A are formed into a general serpentine configuration, although other shapes such as S, V or W shapes will work. Peripheral portions of the reinforcing members 110, 110A extend adjacent to the edge of each compression member. This reinforcing member may also provide for attachment of sutures used to secure the support over a vein. The adjacent edges 120, 120A are secured together by suitable sutures 101 and may also be sutured to the tissue surrounding the vein to prevent the support from becoming dislocated as seen in Figure 8.

The support has a configuration which, when closed as seen in Figures 11 to 11B, provides lateral clearance for the increased transverse width of a valve as vein flattening occurs. The shape of the members 112, 112A may be oval or elliptical (Fig. 11), planar with curved edges (Fig. 11A), or arcuate (Fig. 11B).

The members 112, 112A provide increased surface area to apply the force over a substantial area of the vein and also present a soft surface to the vein. The biocompatible material of the members may be selected having a porosity to allow or permit limited tissue ingrowth. Preferably the support has an axial length of from about 1 to 2 times greater than the width.

The support 100 can be fabricated by starting with a sheet of GORE-TEX® Cardiovascular Patch material and splitting it into separate leafs from opposite edges working toward the middle leaving a non-slit portion of about 2 mm in width which becomes the hinge portion 114. The pre-formed reinforcing members 110, 110A are then inserted into the two slits between the leafs and the assembly is then sealed by compression for about 30 seconds in a hot press that has been pre-heated to a temperature of about 380°C to cause the material to soften and adhere. After cooling, the slit sections attach to one another with the reinforcing member sandwiched between the layers of material.

In Figure 9, a support member 200 is shown which is substantially equivalent in construction to that shown in Figures 6 and 7 having opposed compression members 212, 212A flexibly joined at intermediate hinge section 214. Reinforcing elements 210 and 220 are provided in the compression members. The members are fabricated from a biocompatible material, preferably porous expanded PTFE. In Figure 9, the relieved area 206 is shown as a dome or hemispherical projection located in each compression member at a location to register with the valve sinus area.

Referring to Figure 10, support 300 has opposed compression members 312, 312A fabricated of a biocompatible material and flexibly joined at hinge 314. The members are reinforced by a suitable material such as medical grade stainless steel wire, the reinforcing

elements being designated by 310, 310A. Relief in the sinus areas of the valves is provided by perpendicularly intersecting slits 306, 308 in the members.

In the embodiment shown in Figures 12 to 14, support 400 is again configured having opposite compression members 412 and 412A which may be a surgical grade metal or plastic and have a predetermined rigidity. The members 412, 412A have increased thickness in areas 410, 410A. The opposite members 412, 412A are joined by a hinge section 414 which is a flexible section preferably of the same material. If metal, a suitable stainless steel having the desired flexibility may be selected or the members may be formed from a medical grade polymer such as fluorinated ethylene propylene or polytetrafluoroethylene. The members and the hinge are preferably covered or jacketed with a biocompatible material such as porous expanded PTFE of the type sold under the trademark GORE-TEX® Cardiovascular Patch manufactured by W. L. Gore & Associates of Flagstaff, Arizona. The covering presents a soft, protective surface to the vein. The axial length of the support is from about 1 to 4 times the transverse width.

A locking mechanism 415 is provided opposite the hinge 414. The locking mechanism 415 includes apertures 420 in the free end of the upper member 412 and a pair of tabs 425 extending from the free end of the lower member 412A. The tabs are each provided with a plurality of teeth 430 which may also serve as calibrations. A physician may then engage a selected tooth 430 of each tab in the upper aperture locked by tongues 432 to provide the desired degree of flattening force to the vein. The tongues engage a selected tooth on the tabs to prevent loosening of the support. The support is provided with a relieved area 406 in members 412, 412A at locations to register with the sinus areas.

In Figures 15 to 18, a helical support 500 is shown. To fabricate the support, elongated strips of material such as porous expanded PTFE are spirally wound about a cylindrical mandrel and one or more reinforcing members are wound about the mandrel. The wire is selected to provide reinforcement and strength and MP35N surgical wire has been found acceptable. Any desired number of wires can be incorporated into the member depending upon the degree of compression required. The mandrel is then heated to a temperature in the range of 360°F to 380°C in an air convection oven, causing the porous expanded PTFE to soften and adhere so the wires become embedded as a unitary part of the helical structure. In Figure 17, two reinforcing wires 510 and 511 are shown. The helical structure is then removed from the mandrel and is deformed by compression to assume a transverse elliptical cross section.

In other alternatives, wires 510 and 511 may be provided with an outer covering of another layer of PTFE adhered to the first layer.

The helical structure comprised of a series of helical supports is shown in Figure 15. Five such supports 501, 501A etc. are shown. The helical structure consisting of a plurality of helical supports can be severed at any desired location to separate a single support 501 as shown by Figure 16. The separated support can then be easily placed about the venous valve by elongating it, rotating it about its axis, positioning it and then releasing it, allowing it to return to the helical condition so that it encircles the venous valve, and applying the compressive pressure to achieve a desired flattening. For some applications, a significant length of the helical structure can be used to protect a valve and length of vein against dilatation.

Preferably the support will have a slightly elliptical or oval transverse cross section as best seen in Figure 18, so that the compression force is oppositely applied generally normal to the edges of the valve cusps. This also leaves a clearance area "C" at the opposite sides of the vein for lateral expansion of the vein "V" as compression occurs, as seen in Figure 18.

A preferred material for the substrate of the compression member of Figures 15-18 is porous expanded polytetrafluoroethylene. The commercially available material sold under the designation GORE-TEX® Cardiovascular Patch as manufactured by W.L. Gore & Associates of Flagstaff, Arizona, is a preferred material.

Another advantage of the porous expanded PTFE is that the pore size can be varied in the fabrication technique to facilitate tissue attachment. Also, the density of the material can be controlled and the substrate can be fabricated having varying density with increased density in the area of the surfaces which apply the perpendicular compression force. For more complete discussion of porous expanded PTFE material, see U.S. Patent Nos. 3,953,566 and 4,187,390, herein incorporated by reference.

It will be obvious to those skilled in the art to make various changes, alterations and modifications to the invention described herein. To the extent such changes, alterations and modifications do not depart from the spirit and scope of the appended claims, they are intended to be encompassed therein.

WE CLAIM:

1. An external support for restoring competence to an incompetent venous valve of the type having cusps with free edges and sinuses, said support comprising:

a) first and second opposed compression members having surfaces each with opposite, first and second edges and adapted to extend about at least a substantial part of the exterior of the vein in the area of the cusps of the venous valve and applying an external flattening force generally normal to the coapting edges of the valve cusps,

wherein tension is applied to the cusp edges to restore apposition and competence of the valve; and

b) hinge means connecting the respective first edges of said first and second compression members.

2. The external support of claim 1 further including securing means to connect the respective second edges of the first and second compression members.

3. The external support of claim 1 wherein the venous valve has commissures and wherein said compression members and said hinge form a generally flattened C-shaped cross section wherein the cross section has a transverse width greater than the normal diameter of the vein so as to provide clearance space to accommodate flattening of the vein.

4. The external support of claim 1 wherein said support has an elliptical cross section.

5. The external support of claim 1 wherein said support has an oval cross section.

6. The external support of claim 1 wherein said support has a cross section defined by two arcs.

7. The external support of claim 1 wherein said support is comprised of a biocompatible polymeric material selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, perfluoro alkoxy, polyethylene terephthalate, polypropylene, polyurethane and resorbable polymers.

8. The external support of claim 7 wherein said first and second compression members include a reinforcing member.

9. The external support of claim 8 wherein said reinforcing member is a medical grade wire.

10. The external support of claim 7 wherein said polytetrafluoroethylene is porous polytetrafluoroethylene.

11. The external support of claim 1 wherein said first and second compression members include a reinforcing member.

12. The external support of claim 11 wherein said reinforcing member is a medical grade wire.

13. The external support of claim 1 wherein said first and second compression members include relieved areas to accommodate the sinuses.

14. The external support of claim 13 wherein said relieved areas comprise apertures in each of said compression members.

15. The external support of claim 13 wherein said relieved areas comprise convexities in each of said compression members.

16. The external support of claim 13 wherein said relieved areas comprise two or more slits through each of said compression members.

17. The external support of claim 2 wherein said securing means comprises a surgical suture.

18. The external support of claim 2 wherein said securing means comprises a locking mechanism.

19. An elongated external support for restoring competence to an incompetent venous valve, said venous valve having cusps with free edges, said support comprising compression means adapted to extend about at least a substantial part of the exterior of the vein in the area of the cusps of the venous valve and applying a flattening force to the vein generally normal to the coapting edges of the valve cusps,

wherein tension is applied to the cusp edges to restore apposition and competence of the valve and prevent dilation of the vein.

20. The external support of claim 19 wherein said support comprises a generally helical band formed in a flattened spiral and having at least one reinforcing member.

21. The external support of claim 20 wherein said support is comprised of a biocompatible polymeric material selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, perfluoro alkoxy, polyethylene terephthalate, polypropylene, polyurethane and resorbable polymers.

22. The external support of claim 20 wherein said reinforcing member is a metal wire.

23. The external support of claim 20 wherein said reinforcing member is a biocompatible polymeric material.

24. The external support of claim 22 wherein said reinforcing member comprises two or more parallel wires.

25. The external support of claim 19 wherein said support has an elliptical cross section.

26. The external support of claim 19 wherein said support has an oval cross section.

27. The external support of claim 19 wherein said support has a length and a width wherein the length is about two times greater than the width.

28. The external support of claim 19 wherein said support has a length and a width wherein the length is about five times greater than the width.

29. The external support of claim 19 wherein said support has a length and a width wherein the length is about ten times greater than the width.

30. The external support of claim 19 wherein said support is comprised of a biocompatible polymeric material selected from the group consisting of polytetrafluoroethylene, fluorinated ethylene propylene, perfluoro alkoxy, polyethylene terephthalate, polypropylene, polyurethane and resorbable polymers.

31. The external support of claim 30 wherein said polytetrafluoroethylene is porous polytetrafluoroethylene.

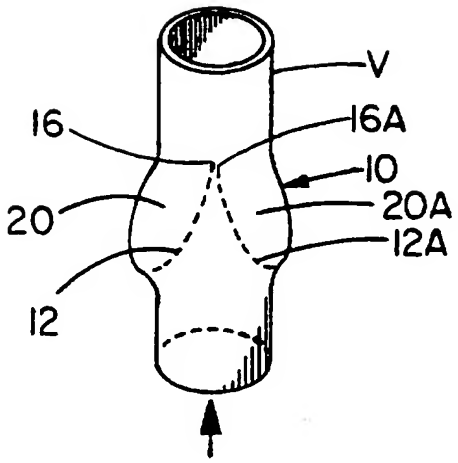

FIG. 1

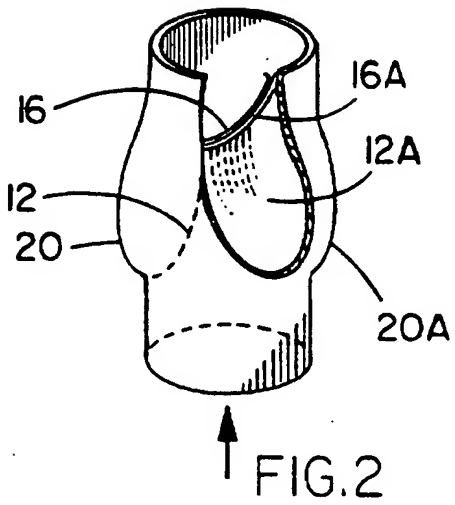

FIG.2

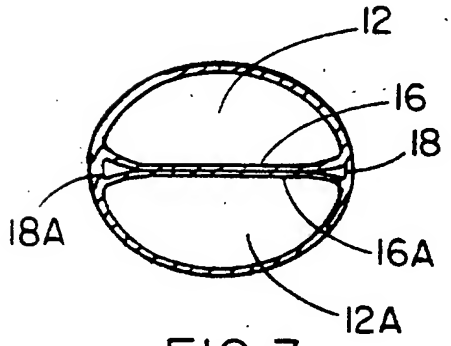

FIG. 3

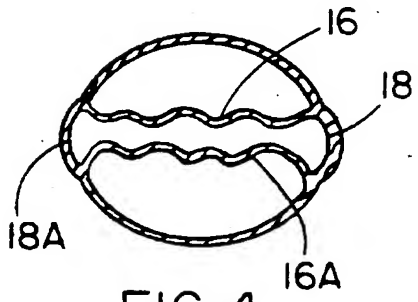

FIG. 4

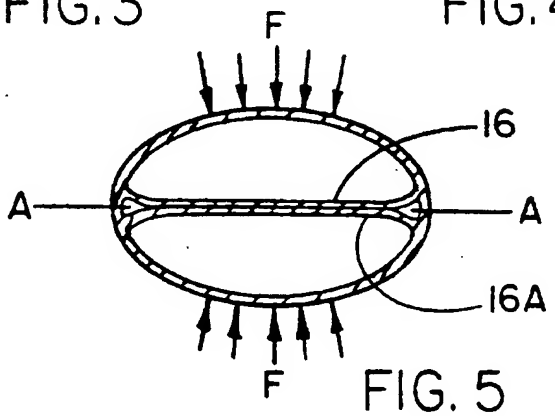

FIG. 5

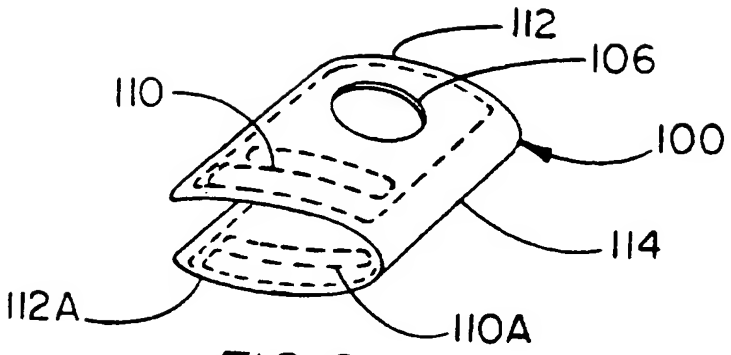

FIG. 6

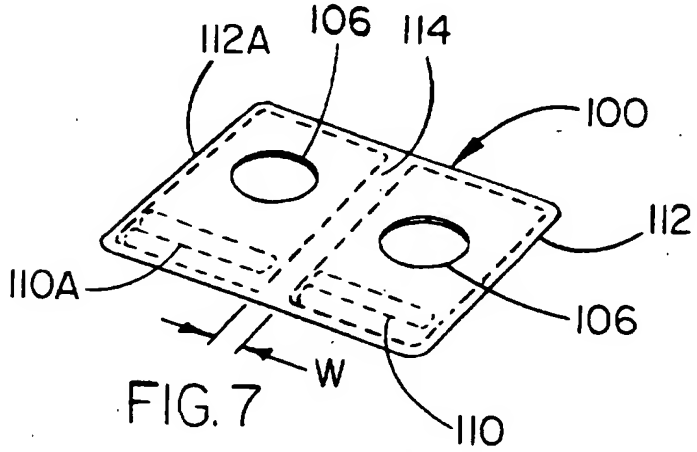

FIG. 7

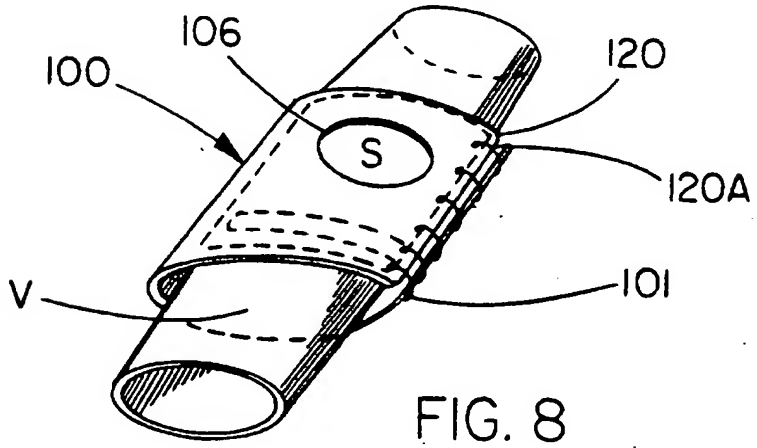

FIG. 8

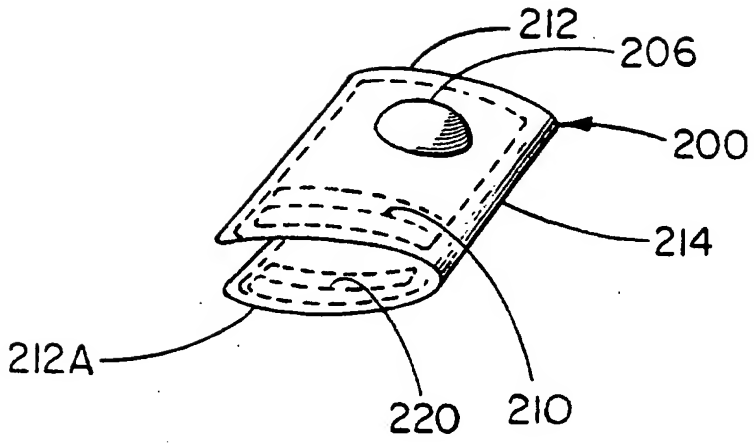

FIG. 9

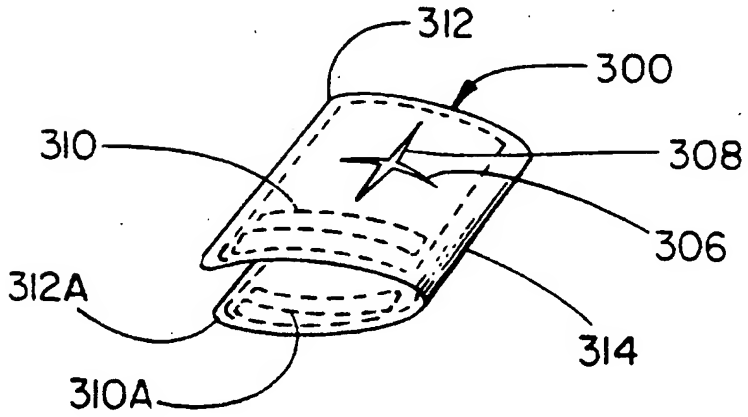

FIG. 10

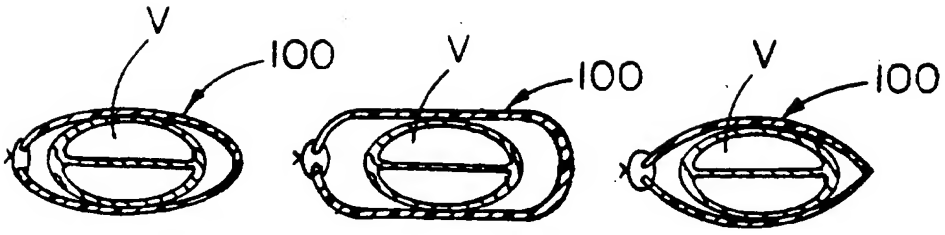

FIG. 11 FIG. 11A FIG. 11B

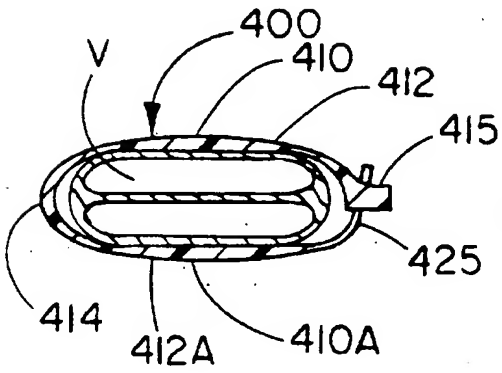

FIG. 13

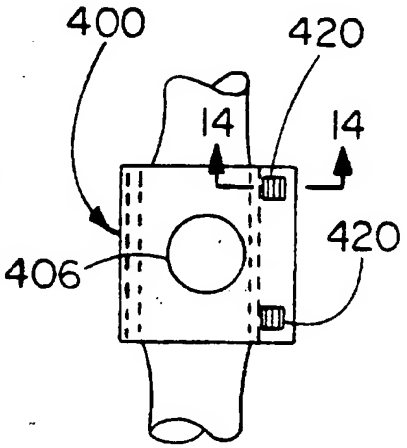

FIG. 12

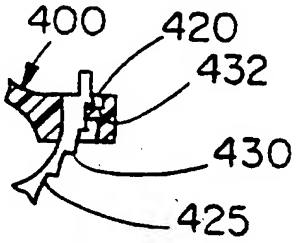

FIG. 14

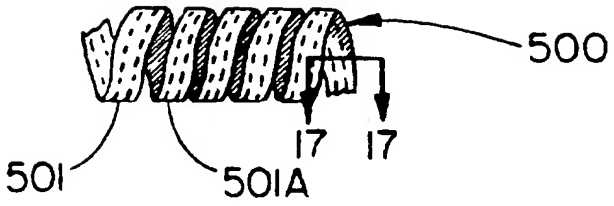

FIG. 15

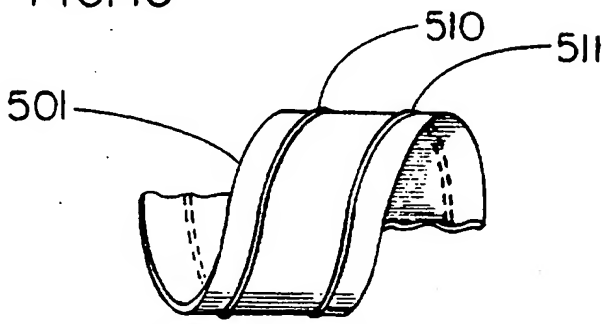

FIG. 16

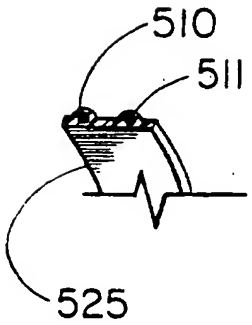

FIG. 17

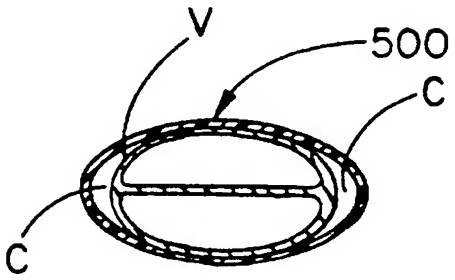

FIG. 18

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/07151

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/122 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 489 446 A (REED CHARLES C) 25 December 1984 see column 4, line 2 - line 66; figures	1-3,5, 18,19, 26,27
A		7,17,25, 30

X	FR 2 688 692 A (SEGUIN JACQUES) 24 September 1993 see page 3, line 78 - page 4, line 114; figures	19
A		1,13,14

A	US 5 476 471 A (SHIFRIN EDWARD G ET AL) 19 December 1995 see column 2, line 18 - column 3, line 2; figures	1,7,8, 19-21, 23,27-30

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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1

Date of the actual completion of the international search	Date of mailing of the international search report
20 August 1997	08.09.1997

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Neumann, E

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/07151

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 586 501 A (CLARACQ MICHEL) 6 May 1986 see column 5, line 5 - line 36; figures see column 1, line 9 - line 11 ---	1-3,7, 10,18, 19,27, 30,31
A	US 5 336 157 A (HALE RALPH) 9 August 1994 -----	

1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. ..onal Application No
PCT/US 97/07151

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4489446 A	25-12-84	NONE	
FR 2688692 A	24-09-93	NONE	
US 5476471 A	19-12-95	AU 7499994 A WO 9505122 A	14-03-95 23-02-95
US 4586501 A	06-05-86	FR 2534801 A EP 0107231 A JP 59131343 A	27-04-84 02-05-84 28-07-84
US 5336157 A	09-08-94	NONE	